

103D CONGRESS  
1ST SESSION

# S. 733

To provide for the immunization of all children in the United States against vaccine-preventable diseases, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

APRIL 1 (legislative day, MARCH 3), 1993

Mr. RIEGLE (for himself, Mr. KENNEDY, Mr. METZENBAUM, Mr. WELLSTONE, and Ms. MIKULSKI) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To provide for the immunization of all children in the United States against vaccine-preventable diseases, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Comprehensive Child  
5 Health Immunization Act of 1993”.

### 6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—

8 (1) CURRENT CIRCUMSTANCES.—Congress  
9 finds the following:

1 (A) Immunizations are among the most  
2 cost-effective means of preventing disease.

3 (B) Although Federal support for child-  
4 hood immunizations has been in existence since  
5 1962, the full potential of immunizations re-  
6 mains to be achieved. Enactment and enforce-  
7 ment of school immunization requirements have  
8 resulted in excellent immunization levels (96  
9 percent or greater) in school children. However,  
10 approximately 80 percent of vaccine doses  
11 should be received before the second birthday in  
12 order to protect children during their most vul-  
13 nerable periods. Many children do not receive  
14 their basic immunizations by that time, and in  
15 some inner cities as few as 10 percent of 2-  
16 year-olds have received a complete series. This  
17 low level of immunizations has been reflected in  
18 recent years by outbreaks of measles among in-  
19 adequately immunized preschool children.

20 (C) The childhood immunization services  
21 delivery infrastructure is both public and pri-  
22 vate. There is considerable evidence to suggest  
23 that the private infrastructure has been eroded  
24 over the past decade as a result of the signifi-

1           cantly increased cost of privately purchased vac-  
2           cines.

3           (D) Prices for privately purchased vaccines  
4           exceed the prices paid for like vaccines in some  
5           other industrialized nations by over 2500 per-  
6           cent.

7           (E) High vaccine costs, coupled with the  
8           growing number of uninsured and underinsured  
9           families, has resulted in private physicians in-  
10          creasingly referring their private-pay patients to  
11          overburdened public clinics for vaccinations.

12          (F) Eleven States now have programs that  
13          provide vaccines without charge to both public  
14          and private health care providers. Other States  
15          that have sought to establish such programs  
16          have been denied additional discounted vaccines  
17          by manufacturers.

18          (G) There is no evidence to suggest that a  
19          negotiated price that takes into account the rea-  
20          sonable cost of production, marketing, research  
21          and development, and distribution will not fairly  
22          compensate vaccine manufacturers. Indeed, a  
23          recent report by the Congressional Office of  
24          Technology Assessment supports the propo-

1           sition that negotiated rates can assure fair com-  
2           pensation while holding down costs.

3           (H) The Secretary of Health and Human  
4           Services has experience negotiating vaccine pur-  
5           chase through the Federal contract system.

6           (I) The National Vaccine Injury Com-  
7           pensation Program is an essential element in a  
8           comprehensive immunization program and  
9           should be applied to additional vaccines rec-  
10          ommended for universal use in children.

11          (2) NEEDED ACTIONS.—With respect to actions  
12          necessary to ensure the full immunization of children  
13          at the earliest possible age, Congress finds the fol-  
14          lowing:

15               (A) The Federal Government should pur-  
16               chase and provide free of charge to health care  
17               providers vaccines recommended for universal  
18               use in children. This action will not only remove  
19               financial barriers to immunization that impede  
20               children from being vaccinated at the appro-  
21               priate time, but will also facilitate the develop-  
22               ment of an immunization tracking system.

23               (B) The Federal Government and the  
24               States should develop linked registries to track  
25               the immunization status of the Nation's chil-

1       dren. The registry system should have the capa-  
2       bility to notify parents of inadequately immu-  
3       nized children of the need to protect their chil-  
4       dren with specific vaccines.

5               (C) The coordinated national information  
6       and education outreach initiative operated  
7       through the Department of Health and Human  
8       Services should be sustained to bring needed in-  
9       formation to parents and health care providers  
10      and focus their attention on the importance of  
11      achieving the full and timely immunization of  
12      children at the earliest appropriate age.

13             (D) Private and public health insurers  
14      should be encouraged to provide adequate reim-  
15      bursement for the administration of childhood  
16      vaccines.

17             (E) Volunteer community activities to pro-  
18      mote the full immunization of children at the  
19      earliest appropriate age should be encouraged.

20             (F) The National Vaccine Injury Com-  
21      pensation Program should be extended and im-  
22      proved. Vaccine information materials should be  
23      simplified to ensure that parents can under-  
24      stand the benefits and risks of vaccines.



1 (b) PURPOSE.—It is the purpose of this Act to ensure  
 2 that all children in the United States are fully immunized  
 3 against vaccine preventable infectious diseases at the earli-  
 4 est appropriate age.

5 **SEC. 3. FEDERAL PURCHASE OF CHILDHOOD VACCINES.**

6 (a) ESTABLISHMENT OF PROGRAM.—The Social Se-  
 7 curity Act (42 U.S.C. 301 et seq.) is amended by adding  
 8 at the end thereof the following new title:

9 **“TITLE XXI—FEDERAL PUR-**  
 10 **CHASE OF CHILDHOOD VAC-**  
 11 **CINES**

12 “PURCHASE BY THE SECRETARY

13 “SEC. 2101. (a) PURCHASE OF VACCINES.—

14 “(1) IN GENERAL.—The Secretary shall regu-  
 15 larly contract for the purchase of vaccines included  
 16 on the list promulgated by the Secretary pursuant to  
 17 section 1931 (referred to in this section as ‘rec-  
 18 ommended childhood vaccines’) in amounts—

19 “(A) necessary for distribution under the  
 20 Public Health Service Act to meet anticipated  
 21 needs for the routine and catch-up immuniza-  
 22 tion of children in the United States in accord-  
 23 ance with the recommendations promulgated  
 24 under section 1931 and for foreseeable out-  
 25 break control activities;

1           “(B) necessary for the maintenance of a  
2           reserve vaccine supply sufficient for a 6-month  
3           period; and

4           “(C) which take into account minimum  
5           waste due to breakage or other unavoidable  
6           losses.

7           “(2) CONSULTATIONS.—

8           “(A)     PREPROCUREMENT     CONSULTA-  
9           TIONS.—The Secretary may consult with rep-  
10          resentatives of State governments, experts in  
11          vaccine delivery, health care providers, and oth-  
12          ers with expertise in purchasing and pricing  
13          pharmaceutical products prior to soliciting bids  
14          or offers for recommended childhood vaccines  
15          under this section. Health care providers shall  
16          also furnish periodic estimates to the States of  
17          the providers’ future dosage needs for rec-  
18          ommended childhood vaccines distributed under  
19          the Public Health Service Act. States receiving  
20          Federal grants for immunization registries shall  
21          report such data to the Secretary. All reports  
22          shall be made with such frequency and in such  
23          detail as the Secretary may prescribe.

24          “(B)     CONSULTATIONS     WITH     FEDERAL  
25          AGENCIES.—The Secretary shall, in order to de-

1           termine the appropriate vaccines and amounts  
2           of vaccines to be purchased under paragraph  
3           (1), consult with Federal agencies involved in  
4           research regarding, or the regulation, procure-  
5           ment, or distribution of, recommended child-  
6           hood vaccines. Such consultation may be ef-  
7           fected through the establishment of a Vaccine  
8           Requirements Panel to be composed entirely of  
9           representatives of the relevant Federal agencies,  
10          or through such other means as the Secretary  
11          determines appropriate.

12          “(3) COST OR PRICING DATA.—

13                 “(A) IN GENERAL.—The Secretary shall  
14                 negotiate a reasonable price for vaccines to be  
15                 purchased under this section that fairly takes  
16                 into account the excise tax under section 4131  
17                 of the Internal Revenue Code of 1986 and the  
18                 various costs described in subparagraph (C).

19                 “(B) MANUFACTURERS.—A manufacturer  
20                 of recommended childhood vaccines shall pro-  
21                 vide cost or pricing data in support of the man-  
22                 ufacturer’s proposed price at the time the man-  
23                 ufacturer responds to a procurement instituted  
24                 by the Secretary under this section. A manufac-  
25                 turer shall also provide such data upon the re-



1 quest of the Secretary whenever the Secretary  
2 determines that contract modifications are nec-  
3 essary.

4 “(C) TYPE OF INFORMATION.—The infor-  
5 mation required under subparagraph (B) shall  
6 include data related to the research and devel-  
7 opment costs of the vaccine, production costs,  
8 handling, shipping, and other costs associated  
9 with delivering the vaccine to health care pro-  
10 viders and States in accordance with the dis-  
11 tribution plan of the Secretary (through the  
12 manufacturers or a State, as the case may be)  
13 under the Public Health Service Act, marketing  
14 costs, profit levels sufficient to encourage future  
15 investments in research and development of new  
16 or improved vaccines, the cost of maintaining  
17 adequate capacity for outbreak control, and any  
18 other data the Secretary determines appro-  
19 priate.

20 “(4) CONFIDENTIALITY OF DATA.—

21 “(A) IN GENERAL.—Information provided  
22 to the Secretary under paragraph (3) shall be  
23 treated as trade secret or confidential informa-  
24 tion subject to section 552(b)(4) of title 5,  
25 United States Code, and section 1905 of title

1 18, United States Code, and shall not be re-  
2 vealed to any person other than those author-  
3 ized by the Secretary in connection with carry-  
4 ing out official duties under this section.

5 “(B) PROHIBITION ON WITHHOLDING.—  
6 Subparagraph (A) shall not be construed as au-  
7 thorizing the withholding of information pro-  
8 vided under paragraph (3) from any duly au-  
9 thorized subcommittee or committee of the Con-  
10 gress. If the Secretary provides such informa-  
11 tion to any subcommittee or committee, the  
12 Secretary shall give written notice to the manu-  
13 facturer that provided the information.

14 “(C) WRITTEN PROCEDURES.—The Sec-  
15 retary shall establish written procedures to en-  
16 sure the confidentiality of information provided  
17 under paragraph (3).

18 “(5) PROHIBITION ON ADDITIONAL SHIPPING  
19 OR HANDLING CHARGES.—Each contract for the  
20 purchase of recommended childhood vaccines under  
21 this section shall contain a provision by which the  
22 manufacturer agrees to ship or otherwise arrange  
23 for the delivery of such vaccines in accordance with  
24 the distribution plan of the Secretary (through the  
25 manufacturers or a State, as the case may be) with-

1 out imposing any additional charge for shipping,  
2 handling, or any other cost on the health care pro-  
3 vider or State to which the vaccine is shipped or  
4 delivered.

5 “(6) MULTIPLE SUPPLIERS.—To ensure a reli-  
6 able and adequate supply of vaccine and to stimulate  
7 competition, the Secretary shall enter into contracts  
8 when feasible with multiple manufacturers of the  
9 same recommended childhood vaccine, under such  
10 terms and conditions and utilizing such procurement  
11 processes as the Secretary determines appropriate.

12 “(7) REPORTING REQUIREMENTS.—Each con-  
13 tract for the purchase of recommended childhood  
14 vaccines under this section shall require the manu-  
15 facturer to report in a standardized form to the Sec-  
16 retary, or the Secretary’s designee, and appropriate  
17 States, at intervals determined by the Secretary,  
18 data regarding the destination of the vaccines by lot  
19 number, and any other information related to the  
20 vaccines purchased that the Secretary may require.

21 “(b) FUNDING.—There shall be made available for  
22 expenditure by the Secretary, out of the Comprehensive  
23 Child Immunization Account in the Treasury of the  
24 United States established pursuant to section 3(b) of the  
25 Comprehensive Child Health Immunization Act of 1993,

1 such amounts as are required to carry out this section  
2 for fiscal year 1995 and for each fiscal year thereafter  
3 during which this section remains in effect.”.

4 (b) FUNDING FOR PROGRAM.—

5 (1) MAINTENANCE OF SEPARATELY IDENTIFI-  
6 ABLE ACCOUNT.—There shall be established in the  
7 Treasury of the United States a Comprehensive  
8 Child Immunization Account for the purpose of  
9 funding the activities under section 2101 of the So-  
10 cial Security Act (as added by subsection (a) of this  
11 section).

12 (2) SOURCE OF RECEIPTS.—Receipts shall be  
13 credited to the account established under paragraph  
14 (1) as may be provided in Federal law.

15 (c) TERMINATION OF PROGRAM.—Such 2101 of the  
16 Social Security Act (as added by subsection (a) of this  
17 section) shall cease to be in effect beginning on such date  
18 as may be prescribed by a Federal law providing for im-  
19 munization services for all children as part of a broad-  
20 based reform of the national health care system.

21 **SEC. 4. REQUIREMENTS CONCERNING IMMUNIZATIONS OF**  
22 **CHILDREN UNDER STATE MEDICAID PRO-**  
23 **GRAMS.**

24 (a) COVERAGE OF IMMUNIZATIONS UNDER EARLY  
25 AND PERIODIC SCREENING, DIAGNOSIS, AND TESTING

1 (EPSDT).—Section 1905(r)(1)(B)(iii) of the Social Secu-  
2 rity Act (42 U.S.C. 1396d(r)(1)(B)(iii)) is amended to  
3 read as follows:

4 “(iii) administration of appropriate rec-  
5 ommended childhood vaccines included on the  
6 list promulgated by the Secretary under section  
7 1931, taking into account the health history of  
8 the individual,”.

9 (b) REIMBURSEMENT RATES FOR RECOMMENDED  
10 CHILDHOOD VACCINES.—Section 1902(a)(13) of the So-  
11 cial Security Act (42 U.S.C. 1396a(a)(13)) is amended—

12 (1) by striking “and” at the end of subpara-  
13 graph (E);

14 (2) by inserting “and” at the end of subpara-  
15 graph (F); and

16 (3) by adding at the end the following new sub-  
17 paragraph:

18 “(G) that payments to providers shall in-  
19 clude amounts, as appropriate, as reimburse-  
20 ment for the administration of recommended  
21 childhood vaccines in accordance with section  
22 1905(r)(1)(B)(iii);”.

23 (c) RECOMMENDED CHILDHOOD VACCINES.—Title  
24 XIX of the Social Security Act (42 U.S.C. 1396 et seq.)  
25 is amended by adding at the end the following new section:



## 1 "RECOMMENDED CHILDHOOD VACCINES

2 "SEC. 1931. Not later than October 1, 1994, (and  
3 periodically thereafter as the Secretary determines appro-  
4 priate in view of advances in scientific understanding in  
5 the areas of immunization and disease control) the Sec-  
6 retary shall promulgate a list of vaccines that provide im-  
7 munization against naturally occurring infectious diseases  
8 and are recommended for universal use in children. The  
9 Secretary shall concurrently promulgate recommendations  
10 regarding the appropriate dosage for each such vaccine,  
11 and the age or ages of children at which each vaccine  
12 should be administered."

## 13 (d) EFFECTIVE DATES.—

14 (1) IN GENERAL.—Except as provided in para-  
15 graph (2), the amendments made by subsections (a)  
16 and (b) shall be effective with respect to calendar  
17 quarters beginning on and after October 1, 1994.

18 (2) EXTENSION FOR STATE LAW AMEND-  
19 MENT.—In the case of a State plan under title XIX  
20 of the Social Security Act which the Secretary of  
21 Health and Human Services determines requires  
22 State legislation in order for the plan to meet the  
23 additional requirements imposed by the amendments  
24 made by subsection (b), the State plan shall not be  
25 regarded as failing to comply with the requirements

1 of such title solely on the basis of its failure to meet  
2 these additional requirements before the first day of  
3 the first calendar quarter beginning after the close  
4 of the first regular session of the State legislature  
5 that begins after the date of enactment of this Act.  
6 For purposes of the previous sentence, in the case  
7 of a State that has a 2-year legislative session, each  
8 year of such session shall be deemed to be a sepa-  
9 rate regular session of the State legislature.

10 **SEC. 5. NATIONAL VACCINE INJURY COMPENSATION PRO-**  
11 **GRAM AMENDMENTS.**

12 (a) **USE OF VACCINE INJURY COMPENSATION TRUST**  
13 **FUND.—**

14 (1) Section 9510(c)(1) of the Internal Revenue  
15 Code of 1986 is amended by striking out “, and be-  
16 fore October 1, 1992,”.

17 (2) Section 6601(r) of the Omnibus Budget  
18 Reconciliation Act of 1989 is amended by striking  
19 out “\$2,500,000 for each of fiscal years 1991 and  
20 1992” each place it appears and inserting in lieu  
21 thereof “ \$3,000,000 for fiscal year 1994 and each  
22 fiscal year thereafter”.

23 (b) **PERMANENT EXTENSION OF AUTHORITY TO IM-**  
24 **POSE TAXES FOR THE VACCINE INJURY COMPENSATION**  
25 **TRUST FUND.—**



1           (1) PERMANENT EXTENSION OF TAX.—Section  
2       4131(c) of the Internal Revenue Code of 1986 is re-  
3       pealed.

4           (2) REINSTATEMENT OF TAX.—The tax im-  
5       posed by section 4131 of the Internal Revenue Code  
6       of 1986 is hereby reinstated effective April 1, 1993.

7   **SEC. 6. NATIONAL IMMUNIZATION TRACKING SYSTEM.**

8       On such date as section 2101 of the Social Security  
9   Act (as added by section 3(a) of this Act) shall cease to  
10   be in effect as provided in section 3(c) of this Act, the  
11   Secretary of Health and Human Services shall implement  
12   a program to ensure participation of all health care provid-  
13   ers in a national immunization tracking system.

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